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EXAMINER				
NGUYEN, HUONG Q				
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3736				
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07/20/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,144

Applicant(s)

ALANEN ET AL.

Examiner

HELEN NGUYEN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 4/26/2010. Claims 1 and 7 are amended. **Claims 1-8 and 11-12** remain pending and under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 1-7** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular regarding Claim 1, it is unclear if the recitation of the distance between the electrodes in the range of about 6 mm to 10 mm is supported by applicant's disclosure. The specification only appears to disclose the broader range of 2 mm to 10 mm, ¶0026, not the more narrow range of 6 mm to 10 mm. Going from a more broad disclosure to a more specific disclosure introduces new matter when said more specific and narrow range has not been explicitly disclosed in the specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-2 and 4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al (US Pat No. 6370426) in view of *Measurement of Dielectric Properties of Subcutaneous Fat with Open-Ended Coaxial Sensors* by Esko et al (hereinafter referred to as "Measurement").
6. Campbell discloses a method for measuring tissue moisture comprising an electromagnetic probe placed on the skin during the measurement and the capacitance of the probe or open-ended coaxial cable is measured to measure the skin water content or edema, best seen in Figure 1 (Col.4: 49-65).
7. However, Campbell et al do not disclose the capacitance of the probe as proportional to the dielectric constant of the skin and subcutaneous fat issue and proportional to the water content of the skin, and is silent to the frequency used, and the size of the probe.
8. Measurement teaches that there is a direct known relationship between the dielectric constant of skin and its water content (p.483 see Discussion second paragraph). Measurement also teaches that a frequency of 300 Hz is used to effectively measure the capacitance of the probe for skin measurements to take into account subcutaneous fat tissue (abst). Measurement also teaches that a larger probe (10 mm) is required to penetrate into the subcutaneous fat tissue (p.479 top).
9. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al such that the capacitance of the

probe is proportional to the dielectric constant of the skin and the subcutaneous fat tissue, which is further proportional to the water content of the skin, to have the distance between the electrodes of Campbell et al be between 2 and 10 mm, and to measure the moisture at a high frequency between 20 MHz- 500 MHz, as taught by Measurement, to effectively perform the skin measurement by taking into account the subcutaneous fat tissue using a properly sized probe and frequency measurement, which would then provide a tissue edema measurement.

10. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al in view of Measurement, and even further in view of Sherwin (US Pat No. 4640290). Campbell et al in combination with Measurement disclose the method described above but do not teach the probe secured to the skin by an attachment such as a strap for continuous edema monitoring. Sherwin teaches using straps as an effective method of attaching a probe to the body of a patient (Col.4, line 15-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al as modified by Measurement to use a strap attachment, as taught by Sherwin, to aid in securing the probe to the skin for continuous monitoring.

11. **Claims 5-6 and 7-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al (US Pat No. 6370426) in view of *Measurement of Dielectric Properties of Subcutaneous Fat with Open-Ended Coaxial Sensors* by Esko et al (hereinafter referred to as "Measurement"), further in view of *Penetration of Electromagnetic Fields of an Open-Ended*

Coaxial Probe between 1 MHz and 1 GHz in Dielectric Skin Measurements by Esko et al
(hereinafter referred to as “Penetration”).

12. Campbell et al disclose a device capable of measuring tissue water content comprising an electromagnetic probe placed on the skin during the measurement, wherein the capacitance of the probe is capable of being proportional to the dielectric constant of the skin and the subcutaneous fat tissue, which is further proportional to the water content of the skin and includes a frequency unit (53) for measuring the capacitance of the probe and a unit (75) for calculating measured values and the tissue water content, best seen in Figure 1 (Col.4: 49-65; Col.5: 43-47). However, Campbell et al is silent as to the frequency used as well as to the distance between the two electrodes of the probe.

13. Measurement teaches that for skin measurements taking into account subcutaneous fat tissue, a larger probe a larger probe (10 mm) is required to penetrate into the subcutaneous fat tissue (p.479 top). Penetration teaches that at higher frequencies above 100 MHz, measured skin measurements take into account deeper skin layers including the subcutaneous fat tissue and at lower frequencies, approximately 20 MHz, the measurements only take into account the more superficial layers of the skin (abst).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Campbell et al such that the two electrodes have a distance of 2-10 mm between, as taught by Measurement, to effectively penetrate into the subcutaneous fat tissue to take said tissue into account for the tissue moisture measurement, which would then provide a tissue edema measurement. Therefore, it would have also been

obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Campbell et al to have the frequency unit measure the capacitance at different ranges wherein at approximately 20 MHz – 50 MHz, the upper layers of the skin are taken into account while at approximately 50 MHz - 500 MHz, the deeper layers of the skin are taken into account as taught by Penetration, to effectively take into account the desired layers for the edema measurement.

15. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Malicki et al (US Pat No. 4918375) in view of Measurement or Penetration or Campbell et al.

16. Malicki et al disclose a method of measuring substrate moisture comprising:
placing a coaxial electrode on a substrate (Col.2: 12-18);
generating a first signal from an oscillator (Col.2: 18-20), wherein the frequency of the first signal is about 20 to 500 MHz (Col.1: 45-46);

transmitting a first portion of the signal of the first signal to the probe and through the substrate (Col.2: 21-24);

receiving a reflected signal from the substrate through the probe (Col.2: 29-31);

leading the reflected signal to a first input of a phase detector;

transmitting a second portion of the first signal to a second input of the phase detector (Col.2: 24-29);

operating the phase detector in a saturated state, wherein signal amplitudes from the reflected signal and the second portion of the first signal form the saturated state;

measuring the phase difference, i.e. time delay, between the reflected signal and the second portion of the signal (Col.2: 31-34);

calculating a dielectric constant from the phase difference (Col.2: 35);

calculating a water content of the substrate based on the dielectric constant (Col.2: 36).

17. However, Malicki et al do not disclose said method used for measuring a water content of the skin such that said probe is placed on the skin during use. Measurement, Penetration, or Campbell et al teach an analogous signal generating method used to measure a water content of the skin wherein a coaxial electrode is placed on the skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method of Malicki et al to measure the water content of the skin as taught by Measurement, Penetration, or Campbell et al, wherein in use the coaxial electrode is placed on the skin and the frequency of the signal used will penetrate the skin and subcutaneous fat tissue (see Measurement and Penetration above), as an obvious useful application of the method.

Response to Arguments

18. Applicant's arguments filed 4/26/2010 have been fully considered but they are not persuasive. Applicant contends that Campbell et al does not measure edema only substrate hydration. However, it is noted that substrate hydration is included in the definition of edema and as such Campbell et al provides a method for measuring tissue edema. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Although applicant contends that Measurement and Penetration

do not disclose measuring edema, it is noted that they provide the relevant teachings pertaining to the distance of the electrodes on the probe as well as how different frequencies of the probe penetrate into different layers of the tissue and thus are still pertinent to the measurement of substrate hydration as taught by Campbell et al.

19. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

20. Furthermore, it is noted that for a proper §103 rejection, "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In *re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). "There is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (*Ruiz* at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (*National Steel Car v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004))." See MPEP 2143.01. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of

ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736